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(54) **Connector for tubing**

(57) The connector includes a co-operating male luer lock connector 34 (Figure 3) and a female luer lock connector 36 (Figure 5); said male luer lock connector 34 having a central tubular portion 50 defining an axial bore 52 with at least a portion of said central tubular portion being enclosed by an outer sheath 56 having a generally circular cross-sectional configuration; said outer sheath being internally threaded; the female luer lock connector 36 comprising a main tubular member 64 and having an outwardly radially extending flange 62 adjacent its distal end; said flange being dimensioned to threadedly co-operate with the internal threads 60 of said male luer connector's outer sheath 56; and a sealing means 80 for providing a pressure seal-like engagement with the internal wall of said outer sheath when the male and female connectors are connected, to aid in maintaining a water tight bacteria barrier at the luer connection.

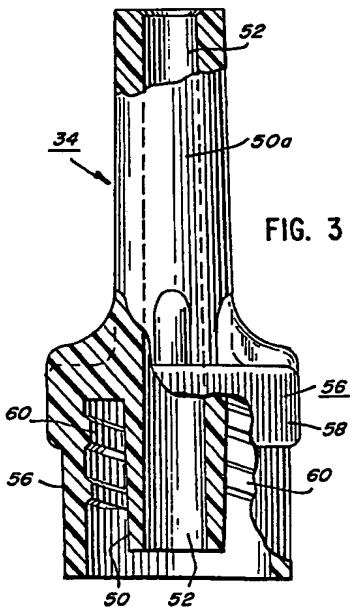


FIG. 3

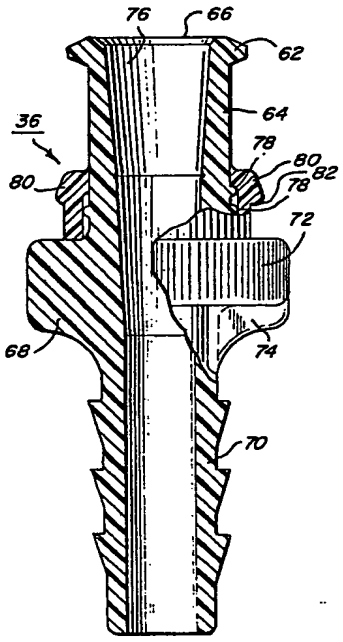


FIG. 6

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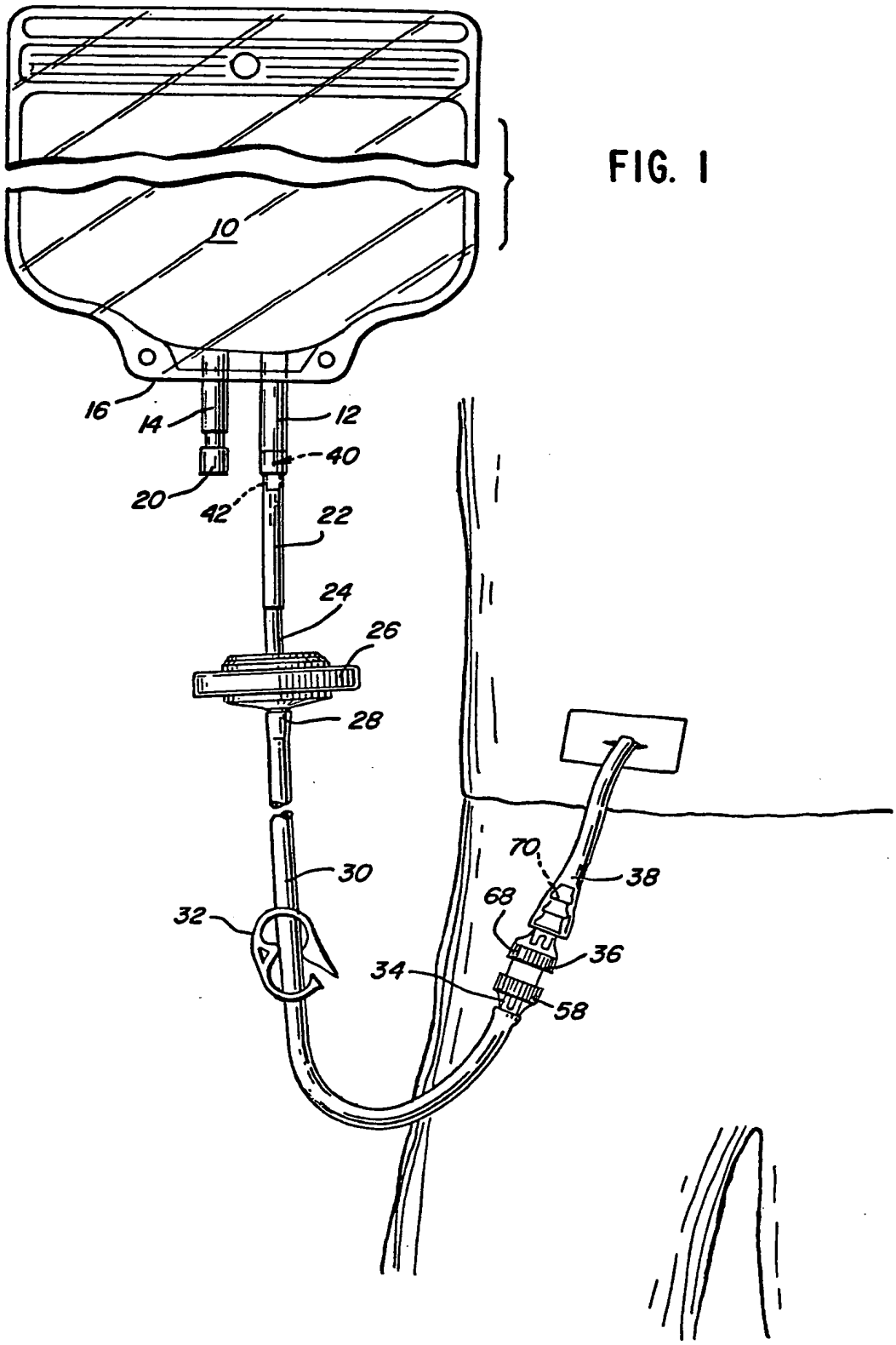


FIG. 1

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FIG. 2

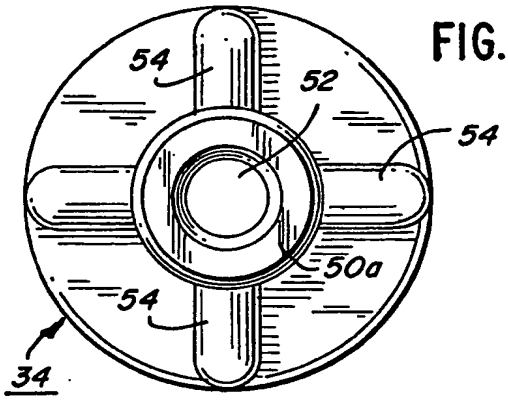
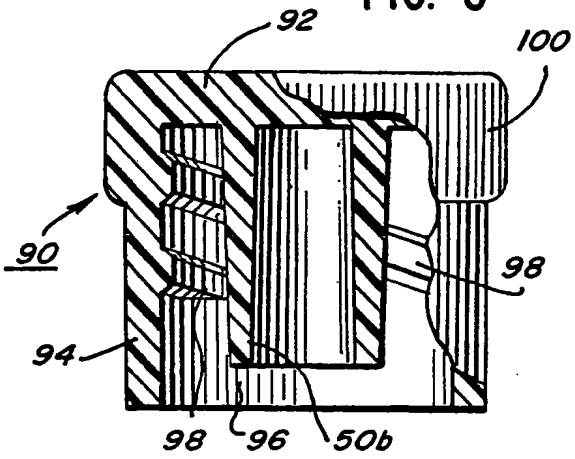



FIG. 8



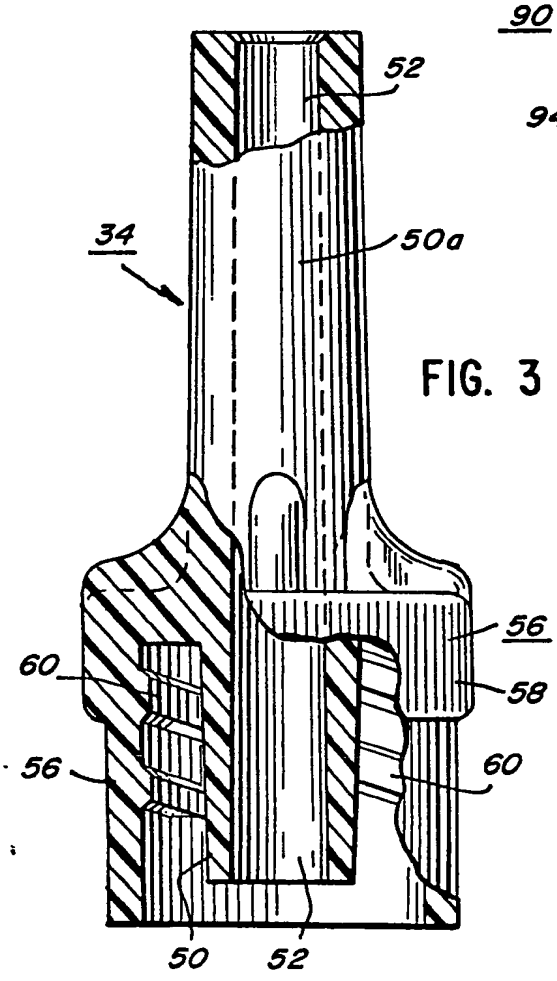
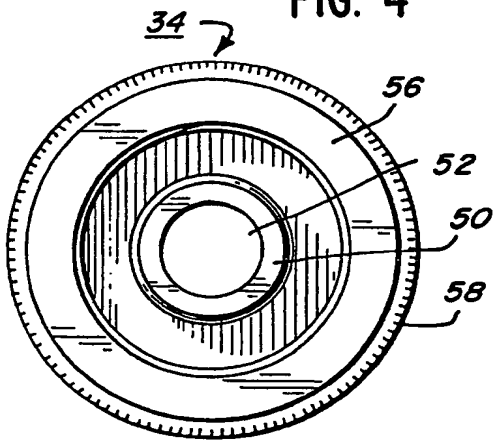




FIG. 3

FIG. 4



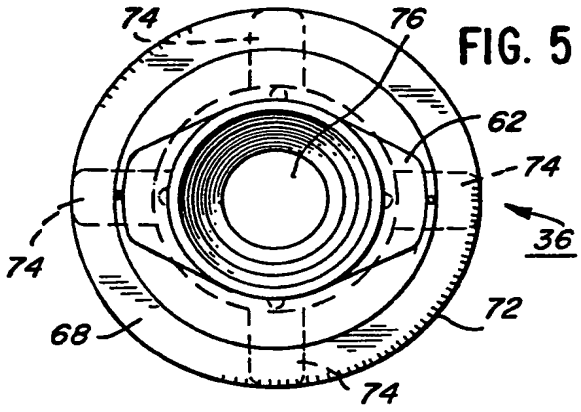



FIG. 5

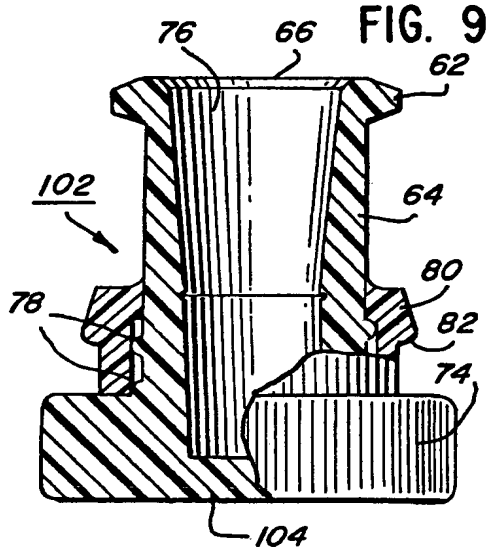



FIG. 9

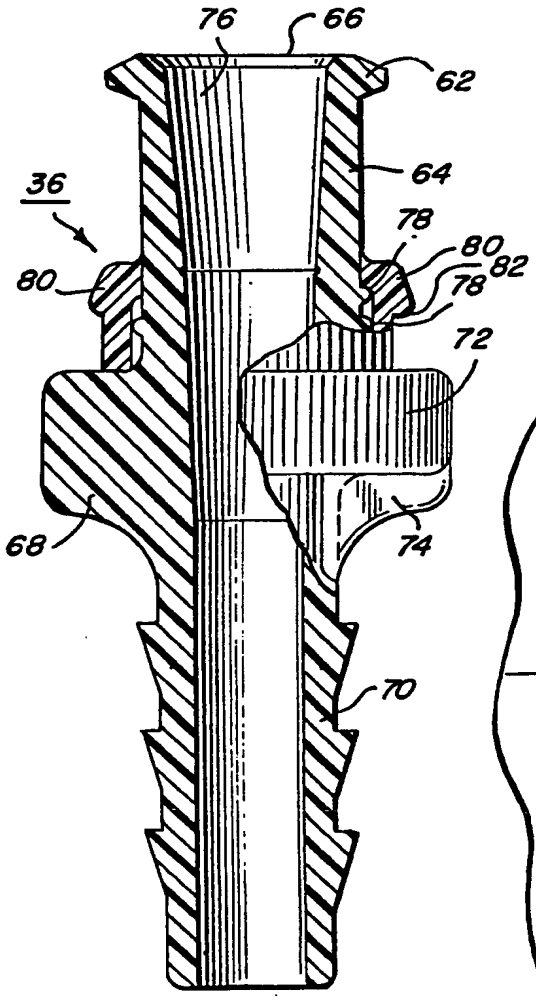



FIG. 6

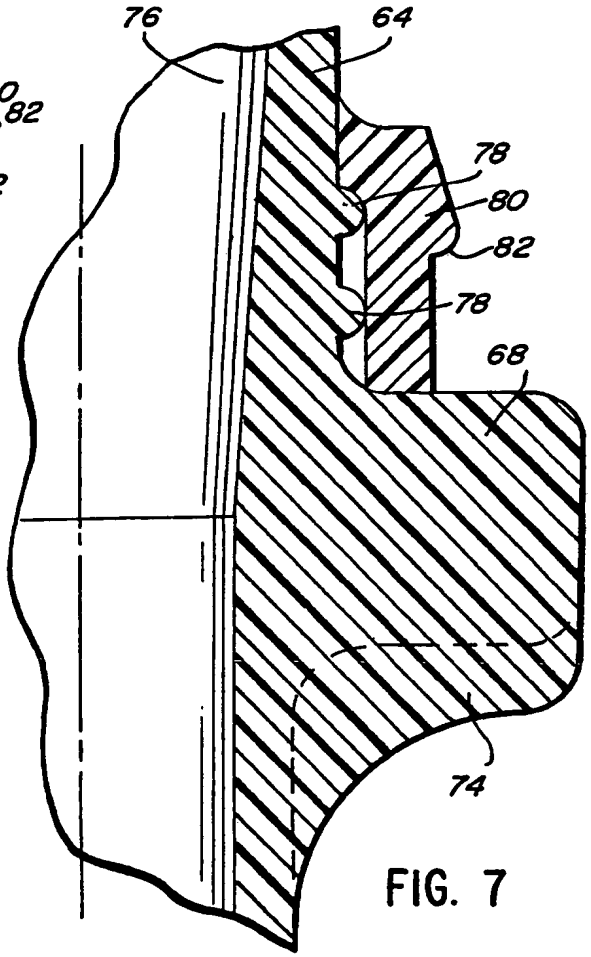



FIG. 7

FIG. 10

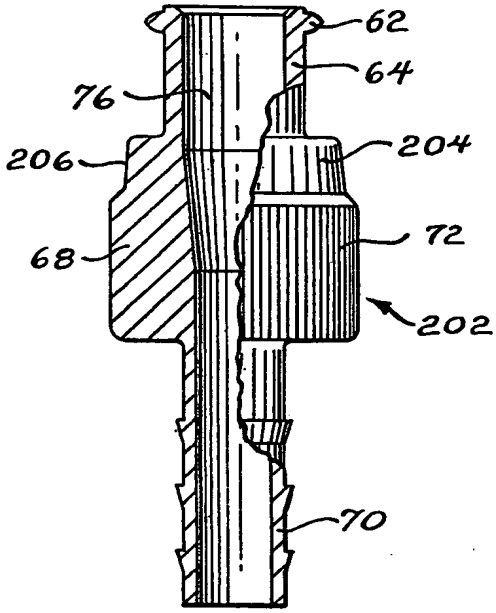

62
64
76
204
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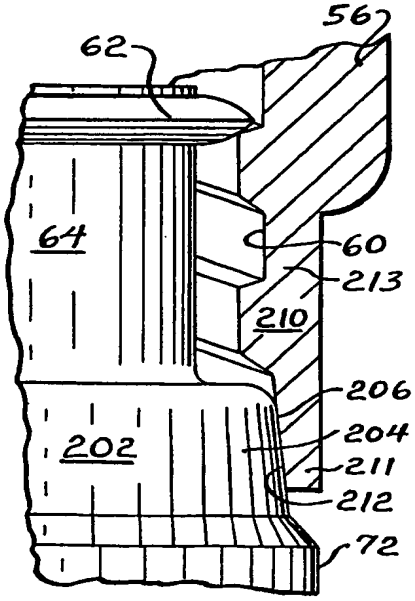
FIG. 11


56
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72

SPECIFICATION

**Solution container for continuous ambulatory peritoneal dialysis**

The present invention relates to a luer lock connection device which is particularly suitable for incorporation in equipment for continuous ambulatory peritoneal dialysis.

The present invention is particularly suited for use in continuous ambulatory perioneal dialysis in which a dialysis solution is introduced to the peritoneal cavity of the patient, allowed to remain there for several hours and then drained from the patient's peritoneal cavity with this process being repeated on a substantially continuous basis. One manner of achieving this type of dialysis includes the steps of connecting a dialysis solution container to a catheter connected to the patient's peritoneal cavity, unclamping the tubing between the dialysis solution container and the patient's peritoneal cavity so as to allow the dialysis solution to flow from the container to the peritoneal cavity, thereafter reclamping the tubing, allowing the dialysis solution to remain within the patient's peritoneal cavity for several hours, for example, four hours, unclamping the tubing and draining the solution from the patient's peritoneal cavity back to the dialysis solution container, disconnecting the dialysis solution container from the catheter tube and connecting to the catheter tube a fresh dialysis solution container, and repeating the aforementioned steps.

We have discovered that the aforesaid process can be enhanced with the patient having greater freedom of movement if the dialysis solution container is in bag form, particularly a flexible, foldable plastic bag. In this manner, once the dialysis solution has exited the dialysis solution bag, the bag can be folded and carried about by the patient. A very effective connection and disconnection system between the dialysis solution bag and the patient's catheter tube can be achieved by using a luer lock connector system. In this manner, the transfer tube extending from the dialysis solution bag carries a first luer connector and the catheter tube extending from the patient's peritoneal cavity carries a complementary luer lock connector. The desirability of achieving, in the absence of liquid, and maintaining an uncontaminated connection at the luer connector is apparent and is achieved by means of the present invention.

It has been found desirable for the luer lock connector which is carried by the patient to be of a relatively permanent type, while the co-operating luer lock connector which is carried by the tubing extending from the solution container may be relatively disposable. Further, it is necessary that the luer lock connection be secure and that leakage be prevented in order to prevent contamination which could result in peritonitis.

Where the dialysis solution bag is such that it carries a transfer tube extending therefrom, which transfer tube couples to the patient's catheter tube, it may be desirable to prevent the dialysis solution within the dialysis solution bag from flowing into the transfer tube carried by the dialysis solution bag. By utilizing a frangible connector in series with the dialysis solution bag tubing the flow of dialysis solution from the dialysis solution bag into the tubing can be prevented until the frangible connector is broken.

According to one aspect of the present invention there is provided a luer lock connection device which comprises: a co-operating male luer lock connector and a female luer lock connector; said male luer lock connector having a central tubular portion defining an axial bore with at least a portion of said central tubular portion being enclosed by an outer sheath having a generally circular cross-sectional configuration; said outer sheath being internally threaded; a female luer lock connector comprising a main tubular member and having an outwardly radially extending flange adjacent its distal end; said flange being dimensioned to threadedly co-operate with the internal threads of said male luer connector's outer sheath; and a sealing means for providing a pressure seal-like engagement with the internal wall of said outer sheath when the male and female connectors are connected, to aid in maintaining a water tight bacteria barrier at the luer connection.

According to another aspect of the present invention there is provided equipment for continuous ambulatory peritoneal dialysis in which a solution container is coupled via flexible tubing to a patient's tube that communicates with the patient's peritoneal cavity, which comprises: a flexible, foldable plastic dialysis solution container having a transfer port extending therefrom; and a flexible tube extending from said transfer port and having a luer connector at its distal end for connecting to a luer connector carried by the patient's tube; and a frangible member in said flexible tube, said frangible member normally blocking fluid flow in said flexible tube but permitting fluid flow after said frangible member is broken.

In the illustrative embodiment, a frangible member is provided in the flexible tube. The frangible member normally blocks fluid flow in the flexible tube but permits fluid flow after the frangible member is broken.

In the illustrative embodiment, a particulate filter is connected in series with the flexible tube. In addition, a manually-operable clamp is connected in series with the flexible tube.

In the illustrative embodiment, the flexible tube has a luer connector at its distal end for connecting to a luer connector carried by the patient's tube. The luer connector at the distal end and the patient's tube luer connector comprise a co-operating male luer lock connector and a female luer lock connector. The male luer connector has a central tubular portion defining an axial bore with at least a portion of the central tubular portion being enclosed by an outer sheath having a generally circular cross-sectional configuration. The outer sheath is internally threaded.

The female luer connector comprises a main tubular member having an outwardly radially extending flange adjacent its distal end. This flange is dimensioned to threadedly co-operate with the internal

threads of the male luer connector's outer sheath.

In one illustrative embodiment, an elastomeric member is carried by the female luer connector and is dimensioned and operable for providing a pressure seal-like engagement with the internal wall of the rigid outer sheath of the male connector to aid in maintaining a water tight bacteria barrier at the luer lock connection. Further, the elastomeric member may be swabbed or the chamber defined by the outer sheath filled with a sterilizing agent by the patient, which would aid in preventing contamination of the system.

Alternatively, in a second illustrative embodiment the female luer connector may have a rigid outer wall portion that is operable with the internal wall of an elastomeric outer sheath of the male connector for providing the pressure seal-like engagement.

In the second illustrative embodiment, the outer wall portion is contiguous with the external surface of the main tubular member and has a rearwardly extending outer taper. In this manner, the pressure engagement of the internal wall of the outer sheath and the outer wall portion will increase as the male and female connectors are threaded together.

In the second illustrative embodiment, the male and female luer lock connectors are each formed in an integral one-piece construction, and the female luer lock connector is formed of stainless steel or titanium to provide a more permanent construction while the male luer lock connector is formed of a resilient plastic material which is readily disposable. It is, of course, apparent that a variety of materials may be used without departing from the scope of the present invention.

Reference is now made to the accompanying drawings, in which:—

Figure 1 is a view of a solution container for continuous ambulatory peritoneal dialysis, constructed in accordance with the principles of the present invention;

Figure 2 is a rear view of a male luer lock connector constructed in accordance with the principles of the present invention;

Figure 3 is an elevational view of a male luer lock connector constructed in accordance with the principles of the present invention, with portions broken away for clarity;

Figure 4 is a front view of the male lock connector shown in Figures 2 and 3;

Figure 5 is a front view of a female luer lock connector constructed in accordance with the principles of the present invention;

Figure 6 is an elevational view thereof, with portions broken away for clarity;

Figure 7 is a greatly enlarged view of a portion of the female luer lock connector of Figure 6;

Figure 8 is an elevational view, with portions broken away for clarity, of a device for capping the female luer lock connector of Figure 6;

Figure 9 is an elevational view, with portions broken away for clarity, of a capping device for the male luer lock connector of Figure 3;

Figure 10 is an elevational view, with portions broken away for clarity, of another embodiment of a female luer lock connector constructed in accordance with the principles of the present invention; and

Figure 11 is an enlarged view of the co-operating portions of the male luer lock connector and the female luer lock connector of Figure 10.

Referring to Figure 1, a dialysis solution bag 10 is shown therein having ports 12 and 14 extending from one side 16 of the bag 10. Port 14 is capped with an injection site 20 in the illustrative embodiment.

Solution container 10 is preferably formed of flexible sheet plastic material that is heat sealed at its edges to form a solution bag. Flexible plastic tubing 22 extends from transfer port 12 and is coupled to the inlet 24 of a particulate filter 26, the outlet 28 of which is coupled to flexible tubing 30 carrying a manually operable clamp 32 in series therewith and having a male luer lock connector 34 at its distal end.

Male luer lock connector 34 is connected to a female luer lock connector 36 which is carried at the distal end of a patient's catheter tube 38 which extends into the patient's peritoneal cavity. Additional details concerning the construction of the luer lock connection system formed by male luer lock connector 34 and female luer lock connector 36 are set forth below and are illustrated in FIGURES 2-9.

A frangible member 40 is positioned in series with transfer port 12 and tubing 22, within the bore defined by the port and tubing. Frangible member 40 blocks fluid flow from transfer port 12 to tubing 22 until the frangible member 40 is broken. Frangible member 40 is preferably formed of a plastic material which fills the flow path of transfer port 12 and tubing 22, but defines a central bore through the plastic material which is sealed by a breakoff member 42. When member 42 is manually broken, the dialysis solution contained by solution bag 10 can flow through the frangible member 40 and thence through tubing 22 and downstream with respect thereto. In this manner, the dialysis solution within solution bag 10 is maintained adjacent transfer port 12 until frangible member 40 is broken, and not until the breaking of frangible member 40 can the solution contained within solution bag 10 flow downstream of the frangible member 40.

The filter 26 is a particulate type filter, having a pore size of approximately 5 mincrons and having a relatively large surface area. It is preferred that the surface area be at least 4 square centimeters and most desirably, about 7 square centimeters. It is also preferred that filter 26 comprise a hydrophilic membrane filter utilizing air venting by hydrophobic membranes.

Clamp 32 may be any type of flexible tubing clamp as is well-known in the art, with it preferably being a type of clamp which may be manually engaged and disengaged, using the thumb and forefinger.

Under certain circumstances, it is believed that certain peritoneal dialysis patients prefer a connection system with respect to the solution container and the patient's catheter tube that does not require the insertion and retraction of a spike connector adjacent the solution container. Unless a spike connector is utilized properly, it is possible that the spike may cause contamination resulting in peritonitis. It

has thus been discovered that under certain circumstances the use of the luer connection system of the present invention is advantageous, and achieves a connection that is less likely to be contaminated.

Male luer connector 34 is illustrated in detail in Figures 2-4. Referring to these Figures, the male luer connector 34 comprises a central tubular portion 50 defining an axial bore 52, and with the central tubular portion 50 defining an axial bore 52, and with the central tubular portion 50 extending rearwardly to form a circular insert 50*a*. Insert 50*a* is solvent bonded within flexible tubing 30 and extends outwardly by means of a plurality of shoulders 54 to provide an outer sheath 56 which surrounds central tubular portion 50. Outer sheath 56 has a knurled manually-graspable portion 58 and carries internal threads 60. The outer sheath 56 aids in preventing touch contamination during locking and/or unlocking of the luer lock connection system and serves to carry the threads 60 which are engaged by a flange 62 (FIGURE 6) carried by female luer lock connector 36.

Referring to FIGURES 5-7 in which the female luer lock connector 36 is shown in detail, it can be seen that connector 36 comprises a main tubular member 64 having outwardly radially extending flange 62 adjacent its distal end 66. A manually graspable ring 68 surrounds main tubular member 64 and is preferably formed integral therewith, with ring 68 also being formed integrally with a barbed rearward extension 70 for bonded connection within the bore of the patients's catheter tube 38. A knurled portion 72 is provided on the external surface of ring 68 to aid in manually grasping the same. Rearward extension 70 is coupled to ring 68 by means of a plurality of shoulders 74, and the central tubular member 64 and rearwardly extending member 70 define a common axial bore 76.

The flange 62 is shaped and dimensioned so that when male luer lock connector 34 is engaged with female luer lock connector 36, central tubular portion 50 of connector 34 will enter bore 76, and flange 62 will be threaded along threads 60 to form a locking connection.

The diameter of bore 76 tapers inwardly from distal end 76, to a diameter that is smaller than the external diameter of central tubular portion 50, whereby an engagement will result between the external surface of central tubular member 50 and the internal wall of tubular member 64.

Referring to FIGURES 6 and 7 in particular, it is seen that a number of projections or rings 78 are carried by tubular member 64 and an elastomeric member 80 surrounds the tubular member 64 and overlies the projections 78. Elastomeric member 80 has an outwardly extending annular bead 82 utilized for sealing purposes. Thus when male connector 34 and female connector 36 are engaged, elastomeric member 80 will enter outer sheath 56 and a sealing action will occur as a result of annular bead 82 engaging the internal wall of outer sheath 56. In addition to providing an effective seal to prevent contamination, elastomeric member 80 also acts to provide a water tight bacteria barrier which maintains the integrity of the locking connection thus preventing contamination of the luer connection.

If desired, elastomeric member 80 could be swabbed or the chamber defined by the outer sheath 56 could be filled by the patient with a sterilizing agent, such as Betadine. It is preferred that the female luer connector 36, with the exception of elastomeric member 80, be formed in a one-piece integral injection molding construction, and that elastomeric member 80 be formed in a subsequent step in the injection molding process during manufacture of the luer connector. Likewise, in this embodiment, it is preferred that the entire male luer connector 34 be formed in a one-piece unitary molded construction.

Referring to FIGURES 10 and 11, an alternative female luer lock connector 202 is illustrated with identical reference numerals indicating the portions of female luer lock connector 202 and male luer lock connector 210 which are identical to portions of female luer lock connector 36 and male luer lock connector 34 respectively.

It can be seen that connector 202 comprises a main tubular member 64 having outwardlyradially extending flange 62 adjacent its distal end. Main tubular member 64 is contiguous with a manually graspable ring 204 which extends contiguously rearwardly from the main tubular member 64, with ring 204 also being formed integrally with a barbed rearward extension 70 for bonded connection with a flexible plastic tube, such as within the peritoneal dialysis. A knurled portion 72 is provided on the rear external surface of ring 204 to aid in manually grasping the same. Rearward extension 70 is coupled to ring 204, and the main tubular member 64 and rearwardly extending member 70 define a coaxial bore 76.

The male luer lock connector 210 used with the female luer lock connector 202 shown in FIGURE 10, is identical to the male luer lock connector 34 shown in FIGURE 3 with the exception that the front end 211 of the outer sheath 213 or the entire outer sheath 213 is formed of an elastomeric material. This may be accomplished by separately molding the outer sheath 213 and then attaching it to a male luer connector or by providing a unitary member formed of the elastomeric material desired.

Outer wall portion 204 of female luer lock connector 202 has a rearwardly extending outward taper 206 so that the pressure engagement of the internal wall 212 of outer sheath 213 of the male luer connector 210 and outer wall portion 204 will increase as the male and female connectors are threaded together.

The flange 62 is shaped and dimensioned so that when male luer lock connector 210 is engaged with female luer lock connector 202, central tubular portion 50 of connector 30 will enter bore 76 and flange 62 will be threaded along threads 60 to form a locking connection. The internal wall 212 of outer sheath 213 will engage tapered surface 206 of outer wall 204 snugly, and the engagement will become tighter as the luer connectors are threadedly closed tighter. In this manner, the cooperation of the internal wall of the outer sheath 213 and surface 206 of outer wall 204 is operable for providing a pressure seal-like engagement to prevent leakage and to aid in main-

taining a water tight bacteria barrier.

If female luer lock connector 202 is coupled to a catheter tube which extends to the patient's peritoneal cavity, it is desirable that luer lock connector 202 be formed of a more permanent material. To this end, a stainless steel or titanium connector 202 would be satisfactory.

Under certain circumstances, the patient may desire to disconnect the luer lock connection once the dialysis solution has been introduced into the patient's peritoneal cavity. For this purpose, a cap 90 (FIGURE 8) for capping the female luer connector is provided which includes a closed top portion 92 and a downwardly extending sidewall portion 94. Sidewall portion 94 defines a bore 96 which has an identical diameter to the opening defined by outer sheath 56, and the internal wall of sidewall portion 94 carries threads 98 which are identical in size and configuration to threads 60. A central tubular portion 50*b* is also provided. A knurled portion 100 is provided for enabling manual grasping of the cap 90.

Referring to FIGURE 9, a cap 102 for capping the male luer connector is provided that is similar in configuration to female luer connector 36 except that it does not include rear tubular connector 70. Identical reference numerals have been used on the FIGURE 9 cap to represent the portions of cap 102 which are identical to portions of female luer connector 36. It can be seen that instead of bore 76 extending continuously, the bore 76 is capped at its end 104. It should also be realized that male luer lock connector 34 may be carried by the patient's catheter tubing 38 with the female luer lock connector 36 being connected at the distal end of tube 30.

As a result of the cooperation of outer sheath 56 and elastomeric member 80, and as a result of the cooperation of outer sheath 211 and outer taper 206, the luer lock connection system has a touch-contamination prevention feature and also utilizes a sealed closure device when connected to provide a water tight bacteria barrier, thereby preventing further contamination.

CLAIMS

1. A luer lock connection device which comprises: a co-operating male luer lock connector and a female luer lock connector; said male luer lock connector having a central tubular portion defining an axial bore with at least a portion of said central tubular portion being enclosed by an outer sheath having a generally circular cross-sectional configuration; said outer sheath being internally threaded; a female luer lock connector comprising a main tubular member and having an outwardly radially extending flange adjacent its distal end; said flange being dimensioned to threadedly co-operate with the internal threads of said male luer connector's outer sheath; and a sealing means for providing a pressure seal-like engagement with the internal wall of said outer sheath when the male and female connectors are connected, to aid in maintaining a water tight bacteria barrier at the luer connection.

2. A luer lock connection device according to claim 1 wherein said sealing means comprises an elastomeric member carried by said female luer connector; said elastomeric member being dimensioned and operable to provide said pressure seal-like engagement with said outer sheath.

3. A luer lock connection device according to claim 2, wherein said female luer connector includes an annular manually graspable ring extending radially outwardly therefrom, said elastomeric member comprising a ring-like member surrounding said central tubular portion adjacent said manually graspable ring toward said distal end of said female luer connector.

4. A luer lock connection device according to claim 1, wherein said sealing means comprises said female luer connector having a rigid outer wall portion that is dimensioned to provide said pressure seal-like engagement with the internal wall of said outer sheath; said outer sheath being formed of an elastomeric material.

5. A luer lock connection device according to claim 4, said outer wall portion having a rearwardly extending outward taper whereby the pressure engagement of the internal wall of the outer sheath and said outer wall portion will increase as the male and female connectors are threaded together.

6. A luer lock connection device according to claim 5 further comprising a knurled, manually graspable portion contiguous with said outer wall portion and tube coupling means extending rearwardly from said knurled portion.

7. A luer lock connection device substantially as described with reference to and as illustrated in any of the accompanying drawings.

8. Equipment for continuous ambulatory peritoneal dialysis in which a solution container is coupled via flexible tubing to a patient's tube that communicates with the patient's peritoneal cavity, which comprises: a flexible, foldable plastic dialysis solution container having a transfer port extending therefrom; and a flexible tube extending from said transfer port and having a luer connector at its distal end for connecting to a luer connector carried by the patient's tube; and a frangible member in said flexible tube, said frangible member normally blocking fluid flow in said flexible tube but permitting fluid flow after said frangible member is broken.

9. Equipment according to claim 8, further comprising a particulate filter in series with said flexible tube.

10. Equipment according to claim 9, wherein said particulate filter has a surface area of at least four square centimeters and includes air venting means.

11. Equipment for continuous ambulatory peritoneal dialysis in which a solution container is coupled via flexible tubing to a patient's tube that communicates with the patient's peritoneal cavity, which comprises: a flexible, foldable plastic dialysis solution container having a transfer port extending therefrom; a flexible tube extending from said transfer port and having a luer connector at its distal end for connecting to a luer connector carried by the patient's tube; and a particulate filter in series with said flexible tube.

12. Equipment according to claim 11, said particulate filter having a surface area of at least four square centimeters and including air venting means.

13. Equipment according to any of claims 8 to 12

including a luer lock connection device according to any of claims 1 to 7.

14. Equipment according to any of claims 8 to 13 further including a manually operable clamp in series with said flexible tube.

15. Equipment for continuous ambulatory peritoneal dialysis substantially as described with reference to and as illustrated in the accompanying drawings.

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